

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL No. 1456
LITIGATION)	
)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:)	
)	Subcategory No. 06-11337-PBS
<i>United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil</i>)	
Action No. 05-11084-PBS)	Hon. Patti B. Saris
)	

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEY DEFENDANTS' MOTION
IN LIMINE TO EXCLUDE FROM EVIDENCE
THE REPORTS AND TESTIMONY OF THEODORE R. MARMOR, PH.D.**

In seeking to exclude the reports and testimony of the plaintiffs' expert, Dr. Theodore Marmor, Dey ignores the most salient fact regarding the admissibility of Dr. Marmor's testimony. Based on his expertise as a professor of public policy, political science and management, Dr. Marmor responds to Dey's argument that the "government" somehow "decided," as a matter of informal and unspoken policy, to reimburse based on inflated AWPs, either to encourage generic substitution or to cross-subsidize purportedly inadequate dispensing fees.¹ *See, e.g.*, Combined Summary Judgment Brief of Defendants Abbott, Dey and Roxane (Master Dkt. No. 1456, Sub. No. 409), 1, 10-16. As there is no evidence the United States ever formally adopted any such policy, Dey has signaled its intent to introduce a broad array of supposed proof, including the informal and nonpublic understanding of agency employees, statements contained in OIG reports, and even Congress's "rejection" of proposals to move the Medicare reimbursement system away from its dependence on AWPs. Dey also plans to

¹ The United States intends to move to exclude such "government knowledge" evidence by way of motions in limine and *Daubert* motions directed at Dey's experts. *See* United States' Motion to Exclude Certain Opinions of W. David Bradford, Ph.D (Master Dkt. No. 6913, Sub. No. 692).

introduce expert testimony (from economists) to explain how the government's response to discovering AWP inflation by many manufacturers adds up to a decision to acquiesce in the practice. If Dey is permitted to introduce such evidence at trial – whether through its experts or through cross-examination of the government's witnesses – plaintiffs are entitled to respond.

Dr. Marmor's testimony will place Dey's "government knowledge" evidence in context. As a political scientist with decades of experience and recognized expertise in the subject of government policy-making, Dr. Marmor is the only expert in this case qualified to opine on how the government adopts and implements policies, and whether the record here is consistent with a decision to approve the reporting of inflated AWPs by drug manufacturers. His testimony is relevant, among other things, to understanding the public and formal process through which government policy is implemented, and to rebut Dey's claim that continued use of AWPs is evidence the government approved of or acquiesced in Dey's practice of setting inflated prices.

ARGUMENT

A. Dr. Marmor's Testimony Responds to Dey's "Government Knowledge" Defense

As this Court has repeatedly ruled, a defense based on government knowledge requires more than showing the government was aware that many AWPs were inflated; rather, Dey must show that the United States approved of or decided to acquiesce in Dey's practice of reporting AWPs wholly unmoored from transaction prices, presumably in furtherance of some policy objective. *See, e.g., In re Pharm. Ind. Average Wholesale Price Litig.*, ____ F. Supp. 2d. ___, 2010 WL 582039, *10 (D. Mass. Feb. 9, 2010) ("To prevail on a government knowledge defense, Defendants must produce admissible evidence that New York or its agencies knew the actual true facts, and that they ordered, asked for, approved, or decided as a policy matter to acquiesce in the Defendants' reporting of false prices"); *Mass. v. Mylan Labs.*, 608 F. Supp. 2d.

127, 148-52 (D. Mass. 2008). Despite extensive discovery, Dey has found no evidence the United States approved of its price reporting conduct through issuance of a policy statement, interpretive memorandum, or any other formal document.

Lacking such evidence, various of Dey's experts infer from the record of government awareness of AWP inflation, and the pace of the government's response to that information, that CMS adopted an *implicit* policy permitting the reporting of inflated AWPs and approving the resultant excessive reimbursement. For example, Dr. David Bradford (one of only two witnesses Dey indicated it expects to call at trial) points to Congressional inaction as evidence Medicare intended to pay inflated drug payments to cross-subsidize dispensing fees. Expert Report of Dr. W. David Bradford, Ph.D ("Bradford Report"), ¶¶ 244-249. Specifically, Dr. Bradford points to Congress's purported failure to adopt 1997 and 1998 proposals by the Clinton Administration to use actual acquisition cost instead of AWP (*id.* ¶ 244-245), and to Congress's suspension of CMS' "inherent reasonableness" authority to reduce payments for various items and services (*id.* ¶ 246). From this evidence, Dr. Bradford concludes, "Ultimately, the drug payments were the result of policy considerations often driven by the Congress that are independent of the published prices." *Id.* , at ¶ 251.²

At bottom, Dey's defense rests on the untested notion that despite the absence of any public pronouncements, the government's adherence to the existing reimbursement scheme in

² Likewise, Robert Helms's expert report addresses the "regulatory performance of state and federal Medicaid agencies with respect to the payment methods used for prescription drugs." Expert Report of Robert B. Helms, ¶ 8. He concludes that CMS recognized "the political role of state legislatures" in setting Medicaid reimbursement rates, and purposefully provided inflated reimbursement to "make up for [] dispensing fees that were not keeping up with the cost of dispensing." *Id.*, ¶ 11. Mr. Helms notes that CMS' attitude towards cross-subsidization was "entirely consistent with the Reagan administration's broad policy goals of limiting federal interference in day-to-day politics and allowing state Medicaid agencies to make their own determinations that would accommodate local political constraints." *Id.*, ¶ 29. It is exactly such policy or "political" conclusions to which Dr. Marmor responds.

the face of its ongoing concerns about the accuracy of the information on which reimbursement was based, reflects a fundamental policy change. Given this argument, the United States is entitled to show, through expert testimony, how government policy is actually implemented. Whether or not “the government” has adopted a particular policy is a question squarely within Dr. Marmor’s specialized knowledge, and his testimony is helpful to understand why it is wrong to infer, as Dey does, that the continued use of a longstanding reimbursement system regardless of a growing awareness that some manufacturers were gaming the system constitutes acquiescence. Expert Report of Dr. Theodore R. Marmor, Ph.D (“Marmor Report”), ¶ 20.

Dr. Marmor examines the history of HCFA’s (now CMS’) policies with regard to drug reimbursement, and employs the broadly-accepted “Allison models” to analyze the government’s behavior in implementing those policies. Initially, Dr. Marmor explains that because the “government” is a complicated organization with an array of constituent parts, *id.*, ¶ 24, it is not properly regarded as a rational, unitary actor and it is improper to draw inferences about government policy from its continued use of a system or its inaction in specific circumstances. *Id.*, ¶¶ 14-15, 19-20. A reliable approach to examining governmental behavior in an area as complex as drug reimbursement should account for, among other things, the government’s past policy, whether that policy was regarded as reasonably satisfactory, and the necessary preconditions to changing the policy. *Id.*, ¶ 21-22, 83-84.

Specifically, Dr. Marmor observes that from its inception Medicare included a “reasonable charge” standard for reimbursing covered services. *Id.*, ¶¶ 30-32.³ He then details various congressional reforms to drug reimbursement, the government’s investigation and

³ Dr. Marmor’s testimony in this regard is entirely consistent with the law as found by this Court and the First Circuit. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 279, 280, 285-286 (D. Mass 2006), *aff’d*, 582 F.3d 156 (1st Cir. 2009).

gradual discovery of AWP inflation by many manufacturers, and assorted proposals intended to rectify the problem. *See, e.g., id.*, ¶¶ 67-84. From this evidence, Dr. Marmor concludes that the continued use of AWPs after the government “knew” they were inflated does not amount to approval or consent but, instead, reflects only that the government “in its many different parts” had yet to agree upon an “alternative reimbursement policy that was practical operationally and acceptable to Congress.” *Id.*, ¶ 86.

In many instances, Dr. Marmor’s testimony addresses the exact same legislative proposals relied on by Dey and its experts. For example, Dr. Bradford implies that Congress’s failure to adopt a 1998 Clinton Administration proposal to reimburse based on actual acquisition costs means the government preferred inflated AWPs. Bradford Report, ¶¶ 244-49. Dr. Marmor explains why Dr. Bradford’s inference is overly simplistic, and provides context for seeing the importance of the 1998 proposal in the evolution of government policy. Specifically, Dr. Marmor notes that the Clinton Administration included similar proposals in its 1999 and 2000 budget submissions. Marmor Report, ¶¶ 80-81. He explains that while these budget proposals did not result in immediate changes to drug reimbursement policy, they did spur three “studies of payment policy implementation” – a form of fact-finding which necessarily delayed reform but was “part of the campaign to transform AWP reimbursement.” *Id.*, ¶ 82.

In sum, Dr. Marmor’s testimony sheds light on the hazards of inferring policy from inaction, particularly with regard to an entity as complicated as the federal government. His testimony also is helpful to understanding the challenges of shifting complicated bureaucracies, *see, e.g., id.*, ¶ 88, particularly when, as was the case with drug reimbursement, the government was acting with incomplete information about the prevalence and extent of AWP inflation. *Id.*, ¶ 92. Such testimony about policy making is admissible. *See Flanagan v. Altria Group, Inc.*,

423 F. Supp. 2d 697, 699-700 (E.D. Mich. 2005) (denying motion to strike affidavit of expert who had studied FTC policies on cigarette marketing over 50 years and whose affidavit opined on how the FTC implemented policies and programs, and concluding that the expert's "specialized knowledge about a complex issue--the FTC's regulation of cigarette advertising and promotion. . . . has been helpful to the Court in explaining the significance of various FTC actions (and would potentially be helpful to a jury as well")). Here, Dr. Marmor's testimony responds directly to Dey's arguments, and will be helpful to the jury if Dey is permitted to argue that government knowledge, even without evidence of formal approval, defeats liability.

B. Dr. Marmor Is Qualified To Opine About Government Policymaking

Although Dey does not take issue with Dr. Marmor's qualifications as an expert directly, Dey suggests he has "no specialized knowledge" concerning the primary subject of his testimony: understanding government decision-making and, specifically, why the record of government knowledge in this case does not amount to approval or acquiescence. Dey is wrong.

Dr. Marmor's original book, *The Politics of Medicare*, and its updated second edition analyzing government healthcare policy through the end of the 1990s, are among the most influential texts addressing the political science of health care legislation. He is widely regarded as a leading authority in the analysis of government healthcare policy and the techniques of such analysis.⁴ Dr. Marmor's research relies on the "methods of political science in constructing accurate and adequate descriptions of government policy-making and non-action." Marmor Report, ¶ 9. This background plainly qualifies him to testify about governmental decision-

⁴ See, e.g., J.S. Hacker, *A Tale of Two Editions: Marmor's The Politics of Medicare and the Study of Health Politics after Thirty Years*, 26 J. Health Pol. Pol'y & L. 120, 121 (2001) (terming Marmor's book "one of the most important founding texts in the field of health politics"); M.A. Peterson, *Lasting Impact*, 26 J. Health Pol. Pol'y & L. 146, 149 (2001) ("Marmor was the first to provide a transportable framework for thinking about and evaluating the role of institutions and politics, as well as ideas and individual decision making, in the making (or failure to make) explicit health care policy").

making generally, and the history of the government's implementation of health care policy in particular.⁵

Dey's real complaint seems to be that Dr. Marmor brings no "specialized knowledge" to the task of defining whether the government approved of or acquiesced in a given policy, and that his testimony does little more than recite the dictionary definitions of "approval" or "acquiescence." Dey Mem. at 2. In Dey's view, the question of whether the government's continued use of AWPs amounts to approval or acquiescence is "based on simple concepts, understandable by any person of reasonable intelligence." *Id.* at 6. Dey describes this inquiry as raising questions "as old as humanity itself," such as "if something is bumped, objects may fall." *Id.* at 5.

Dey's view seriously underestimates the complexity of asking a jury to divine whether the government's response to AWP inflation by some manufacturers constitutes an implicit decision to acquiesce in that practice. The difficulty is particularly acute here, where Dey is asking the jury to infer that an informal policy existed based on the government's continuation of existing reimbursement policy. Many courts have noted the challenges inherent in inferring policy from legislative inaction. *See, e.g., United States v. Craft*, 535 U.S. 274, 287 (2002) ("congressional inaction lacks persuasive significance because several equally tenable inferences can be drawn from such inaction"); *Arnold Tours, Inc. v. Camp*, 472 F.2d 427, 437 (1st Cir. 1992) ("Congressional inaction frequently betokens unawareness, preoccupation or paralysis"); *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 643 F. Supp. 2d 482, 502 (S.D.N.Y. 2009);

⁵ Marmor's primary scholarly works and research have been in the specific field of healthcare policy, with particular emphasis on payment and funding issues. *See, e.g., T. Marmor & D. Thomas, The Politics of Paying Physicians: The Determinants of Government Payment Methods in England, Sweden, and the United States*, 1 Int'l J. Health Servs. 71-8 (1971); Principal Investigator, *Political Analysis: Applications to Health Care and Health Policy*, funded by the Robert Wood Johnson Foundation 2001-2003. Obviously, such research has encompassed pharmaceutical reimbursement.

cf. United States ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 917 (4th Cir. 2003) (identifying “instances in which a government entity might choose to continue funding the contract despite earlier wrongdoing by the contractor”). Indeed, this Court already has ruled that Congress’s failure to act quickly to address the problem of inflated AWPs does not mean it approved the practice. *See In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 187 (D. Mass. 2003) (“the fact that Congress has failed to disturb the widespread practice on the part of pharmaceutical companies of grossly overstating their AWPs cannot be read as a clear and manifest intention to grant immunity from state regulation of such fraudulent practices.”)

If the jury is required to answer such difficult questions, expert testimony on how government operates – that is, how it adopts and implements policies – will be essential. As described above, Dr. Marmor’s testimony addresses the history of government policy-making in the area of drug reimbursement, and will help the jury understand how policy evolved over time, and the difficulty of changing policy in such a complicated and contentious field. In addition, Dr. Marmor’s testimony sheds light on the process by which the government adopts policies, allowing the jury to better evaluate Dey’s claims that the government implicitly acquiesced in its conduct. Courts routinely admit similar kinds of testimony based on expert knowledge of complicated social phenomenon. *See, e.g., Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (accepting testimony of expert in Caribbean social history regarding common knowledge of Puerto Ricans about the health risks of smoking); *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 148 nn.534 & 535 (D.D.C. 2006) (accepting the testimony of an expert in the history of science and medicine). Here, Dr. Marmor’s testimony is based on specialized knowledge of the process of government policy-making, and it will help the jury understand the complicated question of when and how the government makes policy decisions.

C. Dr. Marmor's Opinions Are Based On Sufficient Facts

Contrary to Dey's claims, Dr. Marmor did not merely review materials selected by plaintiffs' counsel. He and his research staff reviewed voluminous evidence and identified pertinent documents, employing the same methods Dr. Marmor would use in drafting an academic article. 2/12/2009 Deposition of Theodore Marmor, 430:7-431:18; 432:21-433:7; 458:22-461:3.⁶ In addition, Dr. Marmor called upon his own understanding of the Medicare program, developed through decades of academic and consulting work. *See generally* Marmor Report, ¶¶ 4-11.

The cases Dey cites in support of its claim that Dr. Marmor did not rely on sufficient facts are inapposite. In *Roussell v. Brinker Int'l, Inc.*, 2008 U.S. Dist. LEXIS 52568, (S.D. Tex. July 9, 2008), the court excluded an expert who was provided with summaries of depositions prepared by defense counsel, only spoke with selected defense witnesses at 5 of the 775 restaurants involved in the litigation (and only in the presence of defense counsel), and left questioning of witnesses to defense counsel. *Id.* at *102, 105. In addition, the court found that the expert's opinions were outside his areas of expertise and relied on a legal interpretation contrary to that adopted by the court. *Id.* at *106, 107. Similarly, in *Lippe v. Bairnco Corp.*, 288 B.R. 678 (S.D.N.Y. 2003), the court rejected a valuation expert who relied solely on counsel to select the supposedly comparable companies used as the basis for the valuation. The expert did not know why the companies were selected, could not explain the qualifications of the person who selected them, and made no effort to ascertain if there were comparable companies that plaintiffs' counsel had not identified. *Id.* at 696-98.

Dey's criticism of Dr. Marmor's relatively few citations to the record developed in this case misapprehends the nature of Dr. Marmor's inquiry, which was whether the government

⁶ Excerpts of Dr. Marmor's deposition are attached as Exhibit 1.

adopted a policy of sanctioning inflated AWPs. By design, his research focused on the public records by and through which governments implement policies. Testimony of CMS officials' understanding of what the term AWP meant is not an official pronouncement of government policy; what agency employees knew, or what positions the agency considered but did not adopt, were simply not relevant to Dr. Marmor's inquiry. *Cf. United States v. Lachman*, 387 F.3d 42, 53-55 (1st Cir. 2004) ("agency interpretations of regulations are only relevant if they are reflected in public documents").

Dey also argues Dr. Marmor's conclusions are fatally flawed because he was not given documents protected by the deliberative process privilege. Although a Special Master reviewed those very documents and found that the overwhelming majority had little or nothing to do with the issues in this case,⁷ Dey contends such information "goes directly to the internal deliberations of the government over drug reimbursement policy and is critical to determining whether the government has approved or acquiesced." Dey Mem. at 10. At bottom, Dey contends that notwithstanding the lengthy public record in this case regarding drug reimbursement, including statutes, regulations, and other formal guidance from CMS, a "secret" policy was spelled out in privileged documents. Both this Court and the First Circuit, however, have ruled on the meaning of Medicare's drug reimbursement regulations, and did so without referencing privileged documents. *In re Pharm Ind. Avg. Wholesale Litig.*, 582 F.3d. 156, 170 (1st Cir. 2009) (noting that Congress and CMS held an "unwavering commitment" to the "policy

⁷ On June 22, 2009, after an "individualized review" of all the documents submitted to him, the Special Master ruled for the Government as to every document except one, a memorandum, a draft version of which had been erroneously produced during a subpoena production by the United States before it became a party in the MDL. He repeatedly described internal CMS documents, the very ones Dey claims Professor Marmor should have reviewed, as "hardly relevant", of "limited relevance", or of "questionable relevance." Mem. and Order on *In Camera* Review of Documents, at 6, 7, 9, 15 (Ex.2). The Court upheld the Special Master's findings over defense objections. Judge Patti B. Saris Electronic Endorsement, Objections to the Special Master's Orders on *In Camera* Review of Documents, (Docket Nos. 6260, 277) *United States ex rel. Ven-A-Care v. Abbott Labs. Inc.*, Nos. 01-12257, 06-11337 (Aug. 31, 2009).

that Medicare reimbursement should be reasonable and reflective of acquisition costs").

In any event, the fact that Dr. Marmor did not review documents protected by the deliberative process privilege does not render his testimony inadmissible. *See, e.g., Spine v. Biedermann Motech GMBH*, 2010 WL 535013, at *27 (D.D.C. Feb. 16, 2010) (expert's failure to review certain documents did not render his opinion unreliable under Fed. R. Evid. 702). Rather, the factual basis for an expert's opinion, including the question of whether that factual basis is complete, goes to the weight of the expert's testimony, not its admissibility. *See Microfinancial, Inc. v. Premier Holidays Int'l*, 385 F.3d 72, 81 (1st Cir. 2004).

D. Dr. Marmor Used Appropriate Models for Analyzing Government Behavior

Dr. Marmor uses the Graham Allison models of government behavior in forming his opinions. Those models gained acclaim in Allison's book analyzing the Cuban missile crisis, but have since been used more broadly in the field of political science as a basis for understanding governmental behavior. Without citing any authority, Dey claims the Allison models are only intended to analyze short-term, one-dimensional events. Dey Mem. at 12-13. Dey ignores, however, that Dr. Marmor and other political scientists have used the models to study long-term patterns of behavior in their academic work. Dr. Marmor explains his use of the Allison models in his academic research and consulting work as follows:

In that work, I have combined the diverse disciplinary methods of history, political science and policy analysis to address . . . explanations and evaluations of public policy developments in the welfare stage generally and in health care policy more specifically. In doing so, I have used the methods of political science in constructing accurate and adequate descriptions of government policy-making and non-action. I have relied upon models of political analysis that clarify what policies are, why they emerge as they do (or not), and what implications follow

Marmor Report, ¶ 9.

As applied by Dr. Marmor in this case, the Allison models provide a useful framework for examining whether the United States decided to replace its formal drug reimbursement policy (set out in statutes and regulations) with an implied policy of tolerating false price reporting to further hidden policy goals, such as subsidizing dispensing fees. Dr. Marmor's testimony reveals that Dey's position – that the government's continued use of AWPs means it condoned manufacturers' false price reporting – employs a model of government behavior (Alison Model I) which assumes the "government" is a unitary and rational actor. In other words, Dey's position only makes sense if one assumes governments act rationally and with a single purpose.

Dr. Marmor explains that because the government is composed of diverse branches, agencies and programs, some of which may at times work at cross-purposes, a Model I account of the government's behavior in reforming drug reimbursement is misleading. A proper model for understanding the federal government's behavior should account for its dispersed composition, which makes it difficult to infer anything about the government's policies without affirmative evidence. Dr. Marmor's report, which employs more nuanced models for evaluating organizational behavior, acknowledges the difficulty of reforming large institutions and the resulting fact that policies, even when known to be imperfect, are likely to change slowly and only when a constellation of events permits serious reform to occur. As Dr. Marmor explains:

it is not enough to note the presence of drug reimbursement problems, allegations of fraud, evidence of individual misdeeds, or public complaining by individual actors and agencies. This body of evidence does not establish either what reimbursement policy in fact was or whether the continuation of particular practices constituted acquiescence or approval. More direct evidence of formal authoritative approval would be required, according to the organizational process model, to establish governmental acquiescence in the type of drug price reporting conduct alleged in this case.

Id. at ¶ 22.

Dey claims that Dr. Marmor's work is not replicable. The term has a different use in social as opposed to applied science, however. Courts have recognized that in social sciences, where naturally occurring circumstances preclude ideal experimentation conditions and controls, "other indicia of reliability are considered under *Daubert*, including professional experience, education, training, and observations." *United States v. Simmons*, 470 F.3d 1115, 1122-23 (5th Cir. 2006) (internal citations omitted) (allowing expert testimony based on research about rape victims developed for therapeutic rather than forensic purposes despite the "inherent limitations" of such research); *United States v. Oussama Abdullah Kassir*, 2009 U.S. Dist. LEXIS 28837, 16-18 (S.D.N.Y. Apr. 2, 2009)(expert permitted to testify about origins, operations and leadership of Al Qaeda organization although methodology not readily subject to testing and permits of no ready calculation of a concrete error rate). Thus, whether Dr. Marmor's work can be "replicated," is not a proper ground to exclude his opinions.

CONCLUSION

For the reasons set forth herein, and as demonstrated by his report and deposition in this case, it is clear that Dr. Marmor's testimony and opinions should be admitted if Dey is permitted to present evidence that the government's continued use of AWPs constituted approval of Dey's practices, or a decision to acquiesce in false price reporting.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification of all parties.

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